K091594

JUN 17 2009

510(k) Summary

flexicare
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Flexicare Breathing Filters Bacterial

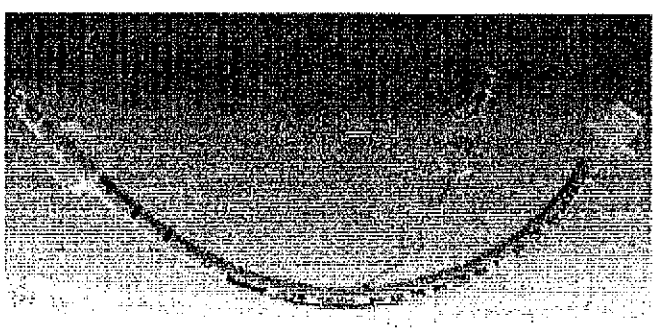
Manufacturer:	Flexicare Medical Limited Cynon Valley Business Park Mountain Ash, Mid Glamorgan CF45 4ER. United Kingdom
Regulatory Affairs Contact:	David Moynham Regulatory Affairs Manager Flexicare Medical Limited, Cynon Valley Business Park Mountain Ash, Mid Glamorgan, CF45 4ER. United Kingdom
Telephone:	00 44 1443 471593
Date Summary Prepared:	30 April 2009
Common Name:	Endotracheal Tube
Classification:	Class II, Tube, Tracheal (W/WO Connector) 21 CFR 868.5730, BTR
Predicative Devices:	Unomedical Sdn BHD K951696 05/22/1995
Description:	Flexicare Medical Endotracheal tubes are available in a number of sizes / variants. The Flexicare Endotracheal tube is a single lumen tube with or without a cuff. The device is used for airway management / gas transport and is connected to a ventilator or resuscitation devices via a connector and breathing tubing. Cuffed variants have an inflatable Cuff, a narrow

	inflation lumen and pilot balloon with valve permitting inflation and deflation using a suitable syringe fitted with a tapered luer connector. All variants (less reinforced) have a radio opaque marker consisting of an axial line embedded into the tube which enables identification the device when patient is x-ray viewed. All variants have a Murphy eye. All variants are supplied sterile and are single use/disposable.
Intended Use:	The Endotracheal Tubes are intended for airway management by nasal or oral intubation of the trachea. They are intended for use on Adult and Pediatric patients.
Substantial Equivalence	The Flexicare Medical Endotracheal Tubes are primarily constructed from polyvinyl chloride. It has the same intended use and design and is manufactured from the similar biocompatible materials as the predicate device.
Summary of Testing:	Flexicare Medical Endotracheal tubes have been evaluated by testing against international standard ISO 5361 Anaesthetic and respiratory equipment – Tracheal tubes and connectors. Both the Flexicare Medical devices and predicate meet the requirements of the ISO standard.

Device Description

The Flexicare Endotracheal Tube is a single lumen tube with or without a cuff. It is intended to be inserted orally or nasally (depending on variant) into the trachea. The device is used for airway management / gas transport and is connected to a ventilator or resuscitation devices via a connector and breathing tubing.

Cuffed variants have a Cuff which is intended to be inflated in the trachea in order to seal the device to prevent loss of inspiratory gases from by-passing the tube and the inhalation of vomit. Cuffed variants have an inflatable Cuff, a narrow inflation lumen and pilot balloon with valve permitting inflation and deflation using a suitable syringe fitted with a tapered luer connector.



All variants (less reinforced) have a radio opaque marker consisting of an axial line imbedded into the tube which enables identification the device when patient is x-ray viewed.

All variants have a Murphy eye.

All variants are supplied sterile and are single use/disposable.

The device is intended for single patient use only.

Intended use:

The Endotracheal Tubes are intended for airway management by nasal or oral intubation of the trachea. They are intended for use on Adult and Pediatric patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2009

Flexicare Medical Limited
C/O Mr. Mark Job
Responsible third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K091591
Trade/Device Name: Endotracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: May 29, 2009
Received: June 2, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091591

Device Name: Endotracheal Tube

Indications for Use:

The Endotracheal Tubes are intended for airway management by nasal or oral intubation of the trachea. They are intended for use on Adult and Pediatric patients.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schutter

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091591